REMARKS

Claims 1-43 are pending in the present application. Claims 2-4, 18-20, 25, 26, 32, 34, 35, and 43 are withdrawn as directed to non-elected species. Claims 1, 8-13, 28, and 33-39 stand rejected as anticipated by Copeland (U.S. Patent No. 4,149,529); Claims 1, 8-11, 33, and 36-38 stand further rejected as anticipated by Mason (U.S. Patent No. 5,080,089); Claims 5-7, 21, 22, and 28-31 stand rejected as obvious over Copeland or Mason, in view of Kelly (U.S. Patent No. 5,383,919); Claims 12-15, 39, and 40 stand rejected as obvious over Mason, in view of Copeland; Claims 16, 17, and 23 stand rejected as obvious over Copeland or Mason, in view of Ruscigno (U.S. Patent No. 4,552,132); Claim 41 stands rejected as obvious over Mason, in view of Copeland, and in further view of Ruscigno; Claim 27 stands rejected as obvious over Copeland, in view of Kelly; Claims 24 and 42 stand rejected as obvious over Copeland or Mason, in view of Goldsmith (U.S. Patent No. 5,407,421). The applicant thanks the Examiner for a thorough review of the present application.

Objection to the Specification

The Examiner has objected to the disclosure, citing the last line of page 7 that continues into page 8 as an incomplete sentence. The referenced paragraph is herein amended, for clarification only, and no new matter has been introduced. The undersigned appreciates the Examiner's assistance.

Distal-to-Proximal Liquid Flow

Prior art devices for providing compression therapies rely generally on providing a compressive force over a treated area (sometimes in combination with thermal treatment) without considering the pressure profile over the length of the pad. In fact, typically, prior art devices locate the fluid inlet port next to the fluid outlet port. As discussed throughout the present application, an important aspect of the invention is that the liquid flow through the bladder is in the distal-to-proximal direction, which provides unique advantages in inducing the

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desired lymphatic flow for users with edema. The distal-to-proximal liquid flow direction naturally produces a pressure gradient that induces the user's lymphatic fluid to flow in a proximal direction. For example, at page 3, line 29, of the present application, the inventor provides a summary that states, in relevant part, a "therapeutic pad and system for treatment of edema are disclosed wherein the therapeutic pad is secured about a portion of the user for applying a pressure that decreases generally from a relatively high pressure at the distal end to a relatively low pressure at the proximal end . . . . This pressure gradient encourages the desired proximal flow of lymph in the user."

The terms "proximal" and "distal" are specifically defined in the present application to be with reference to the user and, specifically, to the direction of lymph flow in the user. For example, at page 6, beginning at line 19, the present application states:

> Throughout this document, the terms "proximal" and "distal" refer in general to the portion of the referenced element that is directed toward the "proximal" or "distal" portion, respectively, of the user when the system is in use, and wherein the lymph is understood to generally flow from a relatively distal portion of the user's anatomy to a relatively proximal portion.

It is therefore intended that the claims, as originally drafted, are limited to an apparatus having an inlet port disposed such that the liquid flow in the bladder is in the same direction as the desired lymph flow.

All of the independent claims (Claims 1, 28, and 33) are herein amended to clarify this important aspect of the present invention. In particular, the independent claims clarify that the proximal portion of the bladder is adapted to be disposed proximally on a user and the distal portion is adapted to be disposed distally on a user. The claims are further amended for clarity to recite that the liquid is provided to the inlet port such that during use the liquid flow through the bladder is adapted to flow from a relatively distal portion of the user to a relatively proximal portion of the user.

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Copeland discloses a "hydraulic appliance 22" with an inlet port 25, which is proximally located, and an outlet port 26, which is distally located. Therefore, the apparatus disclosed by Copeland operates directly opposite from the teachings of the present invention and, to that extent, teaches away from the present invention.

Mason discloses a therapeutic apparatus (shown for a foot) that also does not provide the pressure gradient claimed by the present application. Mason discloses the "apparatus comprises a single containment compartment 8 having two ports 2 and 4 for separate fluid inlet and outlet." In the Figures 3 and 4, the inlet port 4 and outlet port 2 are shown relatively close together on one side of the bladder 9. This arrangement would appear to pressurize the bladder, but thereafter would not generate a flow on the side opposite the inlet and outlet ports.

Because the prior art does not teach or disclose a system for treatment of edema having an inlet port disposed at the distal portion of the bladder (distally with respect to the user), and an outlet port disposed at the proximal portion of the bladder (proximal with respect to the user), such that during use the liquid flow through the bladder is adapted to flow from a relatively distal portion of the user to a relatively proximal portion of the user, the claims are believed to be patentable over the prior art.

Seal Lines Oriented to Direct Flow Proximally to Align With Direction of Lymph Flow

All of the independent claims (Claims 1, 28, and 33) are also amended herein to incorporate the limitations from dependent Claim 6. More specifically, Claim 6 as filed states, "The system of Claim 5 [Claim 5 adds a plurality of flow directing blockages to Claim 1], wherein the flow directing blockages comprise a plurality of seal lines, and wherein the seal lines are oriented to direct the liquid flow proximally to generally align with the direction of the user's lymph flow." As amended herein, seal lines are also clarified consistent with the figures and the specification to recite interior seal lines.

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Although the Examiner does not list Claims 5 and 6 as anticipated on page 2 of the Office Action, it states therein "Regarding claims 5 and 6, the bladder must be sealed around the periphery in order to prevent the fluid from escaping." To clarify the intended scope of the seal lines, the claims are amended to recite "interior seal lines." This is believed to distinguish over any peripheral seal; no new matter is added because all of the seal lines shown in the figures (*e.g.*, 312, 512, 812) are interior seal lines. It will be appreciated that interior seal lines serve a much different function (flow direction rather than fluid containment) in a very different way from a peripheral seal on the bladder.

Page 4 of the Office Action states that "Kelly discloses a therapeutic pad comprising a plurality of spot welds 50 and seal lines 44 . . . ." However, it is respectfully believed that Kelly does not teach or suggest any seal lines.

Referring to Col. 3, beginning at line 16 in Kelly, "separate internal conduits 40 are provided. Preferably, there are two internal conduits 42, 44; one of which reinforces the inlet conduit 30 and one of which reinforces the outlet conduit 30." Element 44, therefore, is an internal conduit 40 for the outlet conduit that extends well outside of the pad 18. As best understood by the undersigned, the two internal conduits (referred to collectively as 40, and separately as 42, 44) are tubes that extend into the inlet and outlet conduits 30, 32, and into the pad 18. In particular, Kelly states at Col. 3, line 65, "The internal conduit is a tube which is slit in a spiral about its longitudinal axis through the tube wall . . . alternatively, the internal conduit may have an open spiral shape such as formed by a plastic coil. Metal coils or springs may be used . . . ."

Kelly does disclose that the internal pocket includes baffles 50, but the only baffles 50 disclosed appear to be circular elements that may be formed by heat welding or adhesives. The only reference to an "elongate baffle" is believed to be at Col. 4, line 33, which indicates an

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elongate baffle may be used to help maintain the position of the conduit 40. Kelly does not disclose a plurality of seal lines oriented to direct liquid flow.

In particular, all of the claims, as amended, recite that the interior seal lines are oriented to direct the liquid flow proximally to generally align with the direction of the user's lymph flow. None of the cited prior art discloses seal lines and, in particular, none of the cited prior art teaches or suggests including seal lines to direct the flow proximally or to direct the flow to align with the user's lymph flow. For this additional reason, the claims are believed to be in condition for allowance.

Claims 5, 6, and 36 are canceled.

Diverging and Converging Flow Deflection

Claim 31 as originally filed recites, in relevant part, "the inlet manifold portion including diverging flow deflection means, and . . . the outlet manifold portion including converging flow deflection means." Diverging and converging flow deflection means in the inlet and outlet manifold portions of a bladder are not found in the cited prior art. The Examiner does not appear to address these limitations. For this additional reason, Claim 31 is believed to be patentable.

Minor Correction to Claims 8, 10, and 11

Claims 8, 10, and 11 include a minor correction (deleting the word "circulating") to avoid the possibility of antecedent basis issues. This change is not believed to change the scope of these claims.

CONCLUSION

The specification is herein amended to correct the error identified by the Examiner. The claims are also amended to clarify and more particularly identify the intended scope of the present claims. Claims 5, 6, and 36 are canceled, and the limitations from Claim 6 have been incorporated into all of the independent claims.

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In particular, the meaning and significance of the distal inlet port and proximal outlet port have been clarified, consistent with the specification, to recite that the claimed apparatus produces a flow and pressure gradient that is proximal-to-distal with respect to the user. This is important to the present invention, as discussed throughout the application, and is believed to be patentably distinct over the cited prior art. In addition, all of the claims now recite a plurality of interior seal lines oriented to direct the liquid flow proximally, to generally align with the direction of the user's lymph flow (or words substantially equivalent). For this additional reason, the claims are believed to be in condition for allowance.

Entry of the amendments and a favorable disposition of the application are respectfully requested. The Examiner is encouraged to call the undersigned at the number below if there remain any questions that might be productively addressed telephonically. The Examiner's continued assistance with this application is greatly appreciated.

Respectfully submitted,

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